

FoEE Biotech Mailout

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TRACEABILITY/LABELLING & NOVEL FOOD/FEED

GMO pollution will be tolerated

Although insiders were unwilling up to the last minute to confirm whether it would happen or not, the European Commission finally managed to adopt its proposals on new EU Regulations for Traceability/Labeling of GMOs and for Novel Food/Feed on Wednesday, July 25th. It turned out to be the most tense day in the GMO political calendar since 14th February when the European Parliament voted on the third reading of the revision of Directive 90/220/EEC. The preceding week saw successive, intense meetings within the Commission with heated debate between the different services that were trying to pull the proposals in one direction or another. Reportedly, the Commissioners were themselves at one stage split right down the middle concerning some of the content.

The work plan of the last meeting of the College of Commissioners before the summer break was particularly busy with other key topics on the agenda such as EU Commission President Prodi's presentation of a White Paper on European Governance. This White Paper is intended to address the problem that EU citizens increasingly distrust institutions and politics or are simply not interested in them, many people are losing confidence in a poorly understood and complex system, and the EU is often seen as remote and at the same time too intrusive. The press

conference by Commissioners Byrne and Wallström to present the proposals, originally scheduled for 12.45H, was postponed repeatedly. Finally, it was after 17.00H when Byrne and Wallström presented the two proposals to the waiting media, following what the Financial Times described as "an often heated two-and-a-half hour debate in which Pascal Lamy, EU Trade Commissioner, and Philippe Busquin, Research Commissioner, led opposition to them".

In many ways, the final version of the texts are actually not significantly different from those described in the last Mailout (*Volume 7, Issue 3, 1.06.2001*). Although environmental and consumer groups are dismayed at the proposal to tolerate (and not to label) 'adventitious' or 'technically unavoidable' presence by unapproved GMOs, there are nevertheless some positive points in the proposed legislation. In brief:

- ☺ The EU will have a traceability system that ensures GMOs can be identified throughout the food and feed chain 'from farm to fork'.
- ☺ The EU will - finally - (at least when the Regulation becomes law sometime around early 2003) have legislation which deals with the authorisation and labelling of GM animal feed.
- ☺ In future, all foods derived from GMOs will be labelled, regardless of whether or not the finished product contains traces of DNA/foreign protein.
- ☺ The simplified notification procedure



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based on 'substantial equivalence' of GM/non-GM is over.

⊗ Both proposals allow for the presence of unauthorised GMOs up to a threshold of 1%, without labelling.

TRACEABILITY & LABELLING

⊙ The proposal for a "Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms" covers:

- all products consisting of or containing GMOs placed on the market,
- foods and food ingredients including food additives and flavourings produced from GMOs,
- feed materials, compound feedingstuffs and feed additives produced from GMOs.

However:

⊗ The scope does not refer to enzymes, despite the fact that many enzymes produced with GM micro-organisms are used in food production.

⊗ Neither does it cover medicinal products for human and veterinary use, leaving open the question of what the regulatory situation would be if at some time in the future GM crops are grown to produce pharmaceuticals or chemicals.

⊗ It does not cover non-food/feed GMOs, although some have already been approved by the European Union (e.g. tobacco) and others are in the pipeline (e.g. cotton).

⊙ For GMOs, pre-packed products placed on the market that consist of or contain GMOs shall be labelled "This product contains genetically modified organisms". At the first stage of placing on the market (including bulk quantities), operators shall ensure that the next operator in the chain is informed of the fact that the product contains or consists of GMOs, and of the unique numeric or alphanumeric code that is assigned to the GMO(s) in question. This information shall be transmitted from operator to operator

throughout the production chain. For products produced from (but not containing or consisting of) GMOs, operators shall ensure that subsequent operators are informed of which of the food ingredients (including additives and flavourings) are produced from GMOs, and which of the feed materials or additives are produced from GMOs. If no ingredient list exists, an indication must be provided that the product is produced from GMOs.

An exemption is provided for the 'adventitious' or 'technically unavoidable' presence of GMOs not authorised for market release in the EU up to a threshold of 1%

⊗ An exemption to the Regulation is provided for the 'adventitious' or 'technically unavoidable' presence of GMOs not authorised for market release in the EU under the deliberate release directive (90/220/EEC revised by 2001/18/EC) up to a threshold of 1%. This exemption is achieved by reference in the Traceability proposal to the Novel Food/Feed proposal wherein Article 42 foresees the amendment of the new deliberate release directive (2001/18), as follows:

ARTICLE 42

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is amended with effect from the date of entry into force of this Regulation as follows:

"The following Article 12a is inserted:

Article 12a

Adventitious presence of GMOs in products

Articles 13 to 21 shall not apply to the placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed, or for processing, in a proportion no higher than 1 % or lower thresholds established in accordance with the procedure laid down in Article 30 (2), provided that these traces of GMOs are adventi-

tious or technically unavoidable and that the GMOs have been subject to a scientific risk assessment made by the relevant Scientific Committee(s) or the European Food Authority, which concludes that the GMOs do not present a risk for human health or the environment.

In order to establish that traces of GMOs are adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid them".

Article 30(2) is a reference to the Regulatory Committee which may decide, on a case-by-case basis, to set the threshold for presence of an unauthorised GMO lower than 1%.

NB: It should be noted that the Traceability & Labelling proposal is not actually the key proposal when it comes to product labelling. The labelling provisions of the T&L proposal are designed to facilitate traceability. The more important labelling provisions are contained in the Novel Food and Feed proposal.

Novel Food & Feed

⊙ The proposal for a "Regulation of the European Parliament and of the Council on genetically modified food and feed" covers:

- genetically modified organisms for food and feed use,
- food and feed containing or consisting of genetically modified organisms,
- food and feed produced from GMOs and food containing ingredients produced from genetically modified organisms.

⊙ It requires all GMOs used for food and feed including:

- GMOs and food/feed containing or consisting of that GMO as well as food/feed produced from or containing ingredients produced from that GMO,
- food produced from or containing an ingredient produced from a GMO as well as foods produced from or containing that food,

- feed produced from a genetically modified organisms as well as feed produced from or containing that feed

to be covered by an authorisation. This signifies a marked improvement over the current situation in which there is no EU legislation covering the authorisation and labelling of animal feed. The only pity is that it will most likely take another 15 months until the proposal passes through the European Parliament and is finally adopted by the EP and the Council before coming into force (i.e. beginning of 2003). In this respect, FoE will continue its campaign for Member States to insist that urgent interim measures are taken to label GM animal feed.

⊗ Once again, an exemption to the Regulation is provided for the 'adventitious' or 'technically unavoidable' presence of GMOs not authorised for market release in the EU under the deliberate release directive (90/220/EEC revised by 2001/18/EC) up to a threshold of 1%. As explained in the previous chapter on Traceability, the exemption is achieved by the amendment of the new deliberate release directive (2001/18).

When unapproved becomes admissible

⊗ The exemptions are dependent on the condition that the unauthorised GMOs have "been subject to a scientific risk assessment made by the relevant Scientific Committee(s) or the European Food Authority, which concludes that this material does not present a risk for human health or the environment". That, in effect, means that the 14 products pending approval against the deliberate release directive (stuck in the pipeline since the EU moratorium on GMO approvals) will be tolerated, without being authorised for market release and without being labelled, up to a level of 1% as long as their presence is deemed to be 'adventitious'.

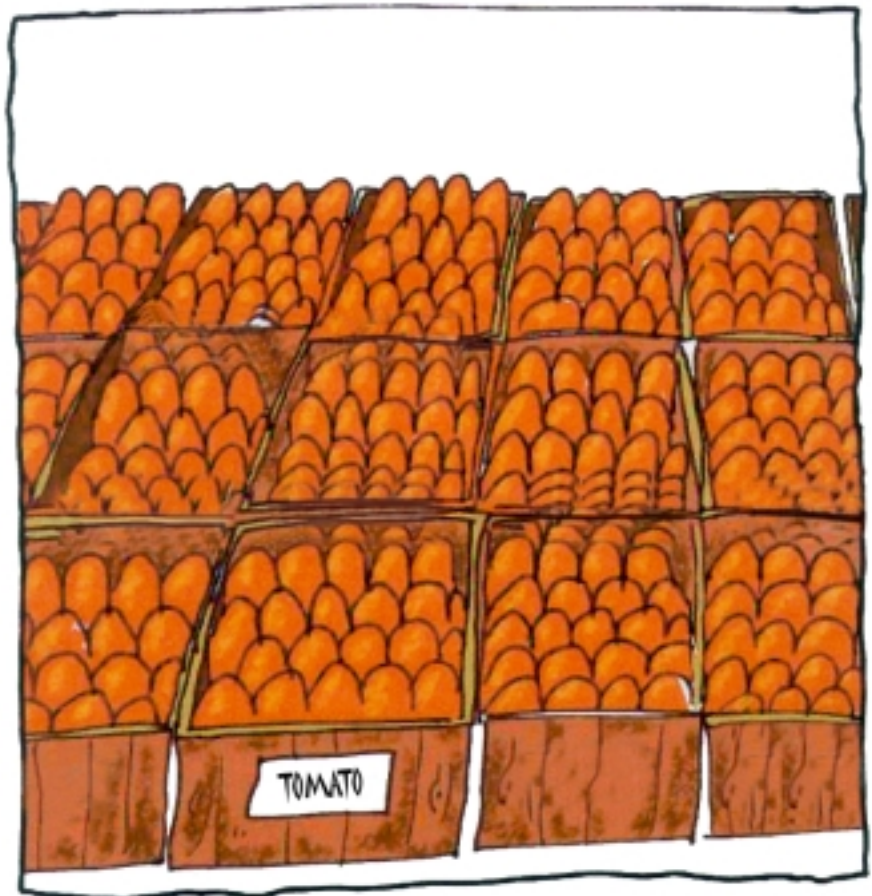
⊗ In order to claim that presence of an unauthorised GMO is 'adventitious' or 'technically un-

Effectively, the products pending approval against the deliberate release directive will be tolerated, without being authorised for market release

avoidable', the proposal says that "operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of genetically modified organisms (or produce thereof)". In this respect, there are concerns in the NGO sector that there is some leeway as to how competent authorities in different Member States will interpret and enforce these "appropriate steps", potentially leading to discrepancies from country to country.

⊗ There is also scepticism in some circles concerning the opinion of the

EU Scientific Committee(s). For a start, the opinions of the SC on the 14 pending products were given under the old deliberate release directive 90/220/EEC, whereas the revised directive 2001/18 requires better risk assessment, taking account of cumulative long-term effects on human health and the environment, including biological diversity and non-agricultural eco-systems. Secondly, with only one exception, the Scientific Committee on Plants has never given a negative opinion on any application for placing on the market of a GM plant. Thirdly, the Scientific Committee on Plants has never upheld any of the objections to placing on the market of GMOs put forward by Member States under Article 16 of Directive 90/220/EEC – a total of eight such objections have been filed by Austria, France, Germany, Greece and Luxembourg.



One in every hundred tomatoes may be genetically modified – unapproved and unlabelled

To say that the Scientific Committee's opinion is 'what counts' implies that the opinion of the Member States themselves is less important

⊗ Furthermore, the notion that the Scientific Committee has delivered a positive opinion on a GMO, and that this GMO is therefore to be tolerated on the market despite the fact that it has not actually received authorisation, undermines the whole approval process itself. It suggests that the opinion of the SC is 'what counts', i.e. that it is more important than that of the Member States whose opinion is required in the Regulatory Committee stage of GMO approvals (and beyond that at Council level if the Regulatory Committee fails to deliver an opinion). To say that the SC's position is enough to consider the GMO 'as good as approved' for market release implies that the opinion of the Member States themselves is less important, and is not likely to be well received in some countries.

One could also imagine a situation where the list of pending products, i.e. those not approved for deliberate release, could grow dramatically, and quickly, with the Scientific Committee delivering positive opinions which would be considered as almost 'tacit approval' even though the Member States have not had an opportunity to deliver their opinion.

The reference to the European Food Authority's opinion is catering for the future since the EFA is still a long way from reality. As mentioned in the last Mailout, the Authority's mandate is still not completely clear, the European Parliament is currently amending the Commission's original proposal, and there is even no firm indication on where the EFA will be located, let alone when it will become fully operational.

Now 'admissible' in small quantities, if 'accidental'

As far as the 14 products pending, and therefore granted an exemption to authorisation and labelling are concerned, these are:

5 GM maize varieties

- Pioneer's insect-resistant (Bt *cryIA(b)*) maize MON 809 – application for all uses, i.e. cultivation, import and processing.
- Novartis' (insect-resistant (Bt *cryIA(b)*) and herbicide-tolerant (glufosinate ammonium) maize Bt 11 - application for cultivation; this maize has already been approved under Directive 90/220/EEC for import and processing.
- Pioneer's insect-resistant (Bt *cryIA(b)*) and herbicide-tolerant (glufosinate ammonium) maize (this is a cross between Aventis T25 + Monsanto MON 810, both of which are already approved under Directive 90/220/EEC) – application for all uses.
- Monsanto's herbicide-tolerant (glyphosate = Roundup) maize GA 21 – application for all uses.
- Monsanto's GA 21 as above – application for import and processing.

3 GM oilseed rape varieties

- AgrEvo's (now Aventis) herbicide-tolerant (glufosinate ammonium) swede rape Falcon GS40/90 – application for all uses.
- Plant Genetic Systems (now Aventis) herbicide-tolerant (glufosinate ammonium) male sterile swede rape MS8, RF3 – application for all uses.
- AgrEvo (now Aventis) herbicide-tolerant (glufosinate ammonium) swede rape Liberator – application for all uses.

2 GM cottons

- Monsanto's insect-resistant (Bt *cryIA(c)*) cotton line 531 – application for all uses.
- Monsanto's herbicide-tolerant cotton line 1445 – application for all uses.

4 other GM plant varieties

- Bejo-Zaden's male sterile chicory – application for food and feed.
- DLF-Trifolium, Monsanto & Danisco Seed's herbicide-tolerant (glyphosate) fodder beet – application for production of seeds and roots, animal feed.
- Zeneca's enhanced shelf life (reduced activity of PG gene) tomato – application for use as a processing tomato.
- Amylogene's altered starch potato – application for use as a starch potato.

Labelling

⊗ EU citizens will certainly welcome the fact that the simplified procedure under the 'substantial equivalence' principle of the current Novel Food Regulation is over. And that the presence of DNA/foreign protein in a finished food product (for example, a vegetable oil) will no longer be a pre-requisite for labelling. The Food/Feed Regulation is quite specific in its labelling provisions:

For Food:

- Where the food consists of more than one ingredient, the words 'genetically modified' or

'produced from genetically modified [name of organism] but not containing a genetically modified organism' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned. Alternatively, these words may appear in a footnote to the list of ingredients. It shall be printed in a font of at least the same size as the list of ingredients.

- Where the ingredient is designated by the name of a category, the words 'contains

[name of ingredient] produced from genetically modified [name of organism] but not containing a genetically modified organism' shall appear in the list of ingredients.

- Where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified [name of organism] but not containing a genetically modified organism' shall appear clearly on the labelling.
- Where the food is offered for sale to the ultimate consumer or to mass caterers without pre-packaging, the information required under this paragraph must be displayed on or in connection with the display of the food.

In addition the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

- Where a food is not equivalent to its conventional counterpart as regards:
 - composition,
 - nutritional value or nutritional effects,
 - intended use of the food,
 - implications for the health of certain sections of the population.
- Where a food may give rise to ethical or religious concerns.

For Feed:

No person shall place a feed referred to in Article 16 (1) on the market unless he ensures that the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto:

- (a) the name of the feed:
- for genetically modified feed the name shall be: "genetically modified [name of the feed]";
 - for feed produced from genetically modified organisms: "produced from genetically modified [name of the feed from which the feed is produced] but not containing a genetically modified organism";
- (b) for feed referred to in Article

16 (1) (b) the name of the feed shall be accompanied by the relevant unique code as established in Regulation (EC).../... of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms;

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 16 (1) such as those indicated hereunder, which is not equivalent to its conventional counterpart:

- composition,
- nutritional properties,
- intended use,
- implications for the health of certain species or categories of animals.

(d) as specified in the authorisation, any characteristic or property where a feed may give rise to ethical or religious concerns.

Consumer choice still not guaranteed

⊗ Although Commissioner Byrne had declared that his objectives with this legislation included guaranteeing that "consumers are able to exercise a choice on the product that they eat", because of the exemptions for unapproved GMOs, consumers will still not be 100% sure that they are not buying and eating GM food. In fact, both approved and unapproved GMOs will be tolerated up to a threshold of 1% without labelling. In a practical example, it effectively means that one in a hundred tomatoes, or potatoes, could be genetically modified without any need to label.

☺ On the other hand, it could have been even worse. As men-

Those in the Commission who held out against pressure and put environmental and consumer concerns above trade threats should be congratulated

tioned in previous Mailouts this year, earlier drafts of the proposed legislation had indicated that 'adventitious' or 'technically unavoidable' contamination by GMOs approved in third countries, or authorised only for Part B (experimental) release in the EU would have been tolerated. This would have opened up the door for some 50 varieties approved in North America (US and Canada) and for many other GM varieties that are only authorised for experimental trials. Those in the Commission who held out against pressure from overseas governments should be congratulated for putting environmental and consumer concerns above trade threats. And those who defended the principle of labelling regardless of DNA/foreign protein presence in finished products, as well as putting an end to the contentious "substantial equivalence" of GM and non-GM products, deserve a pat on the back too. These are believed to have been some of the most fiercely contested issues within the Commission itself, with strong opposition from the usual protagonists such as the Trade, Enterprise, Research and Competition directorates.

The process now passes to the European Parliament which is expected to treat Traceability & Labelling, Novel Food & Feed, and the revision of Directive 2001/18/EC as a single 'package' with one rapporteur. After the summer break, the Member States will also make their view known on the proposals. Some – Belgium, Denmark, Finland, France, Italy and Portugal – were reportedly not in favour of revising the deliberate release directive, and several, e.g. the 'moratorium' countries, are likely to be against the 1% threshold for unapproved GMOs.

The texts of the proposals for both Regulations as well as the press statement of the Commission can be found on the following web site: http://www.europa.eu.int/comm/food/index_en.html

GMO CONTAMINATION IN SEEDS TOO

Background

The European Commission's White Paper on Food Safety (COM (1999) 719) requires amendments to be made to the Annexes of the current Directives on the marketing of seeds, i.e. Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458 on the marketing of beet seed, fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable seed. These amendments are intended to lay down:

- growing conditions and other requirements for purity concerning the adventitious presence of genetically modified seeds in seed lots of conventional plant varieties;
- details of the labelling requirement as established by Council Directive 98/95/EC (the 'seeds package directive') for seeds of genetically modified plant varieties.

In January 2001, the Commission published its Working Paper (WP) on the "Adventitious presence of GM seeds in seed of conventional plant varieties". The WP took as a basis the threshold of 1% established for the adventitious presence of food ingredients derived from GMOs (Commission Regulation (EC) 49/2000). Given this threshold, the WP proposed a GM seed threshold of 0.3% for cross-pollinating varieties, and of 0.5% for self-pollinating varieties and vegetatively propagated crops. Crucially, "GM seeds not covered by an authorisation under part C of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms are not allowed and should therefore not be present in the seed lot". Moreover, the WP proposed to strengthen seed production stan-

dards and to introduce two labels: "EU-unauthorised genetically modified organisms not present" and "genetically modified variety".

On 7th March, the EU's Scientific Committee on Plants (SCP) adopted its opinion concerning "the adventitious presence of GM seeds in conventional seeds". As reported in FoEE Biotech Mailout Volume 7, Issue 2, 1.04.2001, the SCP was generally dismissive of the proposals put forward in the Commission's WP. Under the (questionable) assumption that GM crop production will increase in Europe, the SCP argued that "in due course, the 1% threshold set by the Commission may have to be revised" and that "a zero level of unauthorised GM seed is unobtainable in practice".

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The Commission's draft proposal

Since March this year, DG-SANCO has obviously collaborated closely with the seed industry and held two meetings with the major seed companies during May. On 21st June, the Commission held the first consultation with both industry and other stakeholders such as NGOs. It transpired that a draft proposal for a Directive* already existed and that industry representatives had received copies of the proposal whereas the NGOs either did not have it or had received an 'unofficial' copy only very recently. DG-SANCO nonetheless declined to circulate the draft proposal during the meeting.

(* Draft "Commission Directive

amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458 on the marketing of beet seed, fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable seed tatoes, seed of oil and fibre plants and vegetable seed", 25.05.2001.)

Unauthorised GM seeds

The Commission's draft proposal sticks to the original demand that unapproved GM seeds should not be present in a seed lot. However, in one of the recitals the proposal states that the zero tolerance for unapproved GMOs should be "adapted" in accordance with the future EU regulation on traceability which foresees an amendment of Directive 2001/18/EC to exempt 'adventitious' or 'technically unavoidable' GMO contamination from the scope of the Directive. As we now know (see cover article in this Mailout), the recently tabled proposals for Regulations on Traceability of GMOs and for Novel Food/Feed do indeed foresee revision of 2001/18 in order to allow the presence of unauthorised GMOs.

Contamination with authorised GM seeds

Thresholds

With regard to seeds of GMOs that have been authorised in the EU, the Commission modifies its approach:

- 0.3% for cross-pollinating varieties/species other than maize, field peas, beet and vegetable varieties propagated from seed but cultivated vegetatively;
- 0.5% for self-pollinating varieties/species other than soya bean and for maize, beet and vegetable varieties propagated from seed but cultivated vegetatively;

- 0.7% for field peas and soya.

Isolation Distances

The Commission drops its proposal to double the distances currently applicable to the isolation of crops for seed production. The draft proposal only refers to "good practice for seed production". However, for beet an isolation distance of 2000m shall be required; for hybrid swede rape and turnip rape, an isolation distance of 5000m or 3000m shall be required depending on whether basic or certified seed is produced.

Previous cropping requirements

Originally, the Commission proposed more stringent previous cropping requirements than currently foreseen. The draft proposal requires such an extension only for specific species such as peas, sugar beet and oilseed rape. However, this proposal which follows the recommendation of the SCP is not based on science. In fact, the SCP stated explicitly in its Opinion that there "is a lack of clear scientific data on persistence times for some species and therefore reliance is placed on anecdotal evidence and seed production experience."

Labelling

Whereas the Commission's Working Paper had proposed two forms of labelling: "EU-unauthorised genetically modified organisms not present" and "genetically modified variety", one of which would have to be used, the draft proposal foresees only a label for genetically modified varieties. The Commission drops the label "EU-unauthorised genetically modified organisms not present" in anticipation of an amendment of Directive 2001/18/EC which would allow unauthorised GM seeds to be present in conventional seeds.

Conclusion

In its current form, the Commission's draft proposal is unacceptable for the following reasons:

- It calls for an amendment of Directive 2001/18/EC to allow for the adventitious release of

unauthorised GM seeds (an amendment also foreseen in the proposals for Regulations on Traceability and Novel Food/Feed see p. 1-5)

- Instead of requiring breeders and farmers who multiply/cultivate GM seeds to take all the necessary measures to avoid GM pollution, the proposal puts the whole burden on those breeders and seed multipliers who do not propagate GM seeds.
- The previous cropping requirements are based on 'anecdotal evidence'.
- The reference to "good practice for seed production" is not helpful to avoid GM contamination since there is no agreement concerning such practice and insufficient experience with regard to GM contamination. Isolation distances and previous cropping requirements are supposed to be measures that the seed industry has to take in order to benefit from the privilege of the threshold for 'adventitious' or 'technically unavoidable' contamination. Therefore they have to be defined in detail and uniformly applied within the Community.

The final proposal for the Directive is not expected to be ready until the autumn.

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STARLINK IS NOT OK

A advisory panel of scientists mandated to advise the US Environmental Protection Agency (EPA) on the safety of Aventis StarLink GM maize has ruled that it is not safe for use in food. Although there is a low risk that consumers would eat enough to develop an allergy, the scientists said they believe that there is a medium chance that StarLink is an allergen and that too many questions remain about whether the maize can cause rashes, breathing problems and other allergic reactions. The 16-member panel's conclusions were announced on Friday, 27th July. The EPA had commissioned the scientists to investigate StarLink's impact on human health following the scandal which erupted last September when the GM maize, which was only approved in the United States for use as animal feed was found to be present in food products (*see FoEE Biotech Mailout Volume 6, Issue 7 and Volume 7 Issues 1 & 2*).

Since the discovery of StarLink in human food, Aventis has been forced to withdraw the product from the market. According to the US Department of Agriculture, it has 'accounted for' all but 720,000 of the 128 million bushels of StarLink that were in circulation. Government officials have been quoted as saying that it will be 4 – 5 years before StarLink has been eliminated from the food supply. But Aventis has been lobbying the US authorities intensively to re-consider StarLink's approval status for human food in order to alleviate its product recall problems. The company wants the EPA to allow a small amount (20 ppb, or one in 800 grain kernels) of StarLink in food products as a convenient means of solving their problem. Aventis claims that any contamination of human food by StarLink would be in such small

amounts as not to pose any threat to human health. However, the panel of scientists advising the EPA concluded that insufficient data is available to be certain that the genetic modification in question, the *Cry9c* protein which is toxic to insects, is safe and will not cause allergies. They also questioned the ability of an antibody test to detect *Cry9c* in some processed foods.

Until recently, it had been thought that StarLink contamination of the human food only extended to yellow maize products. However, a few weeks ago, the US Food and Drug Administration (FDA) contacted the supermarket chain Kash 'n Karry to warn them that genetic material from Starlink had been detected following tests the agency carried out on tortilla chips manufactured from white maize. As a result, Kash 'n Karry withdrew its white maize tortilla chips from their shelves, as did another chain Food Lion. Both are owned by the Belgian food giant Delhaize.

One of the witnesses who gave evidence to the scientific panel advising the EPA was Dr. Keith Finger, an optometrist from Florida. He was one of 17 people whose blood was tested earlier this year by the Center for Disease Control and Protection (CDC) to detect any special sensitivity to *Cry9C*. Dr. Finger told the panel that he suffered a severe allergic reaction after eating just a few of the maize chips – the rest of the bag was given to the FDA for analysis and was the only sample out of a total of eleven submitted by allergy-test subjects that tested positive for contamination by StarLink. Dr. Finger, who described his condition as "life-threatening", showed the scientific panel pictures of the welts and rashes which developed on his body, and said that, after eating the chips, he woke in the middle of the night and had to go to a hospital's emergency department for treatment.

Dr. Finger described his condition as "life-threatening" the scientific panel suggested that the government data on self-reported allergic reactions might fall far short of actual cases

Dr. Finger's blood sample had tested negative in analyses organised by the CDC, as had those of the 17 others whose blood was analysed. However, the validity of those tests has been thrown into question by some of the scientists on the EPA's advisory panel. According to reports in the US press, some members of the panel doubted the effectiveness of the test, expressing concern that the results of the blood tests may not even be representative because the *Cry9C* used in the tests was not derived directly from StarLink. "It reduces our concern, but cannot eliminate our concern about these individuals reacting to *Cry9C* protein" said Dean Metcalfe, one of the panel members.

Some scientists also questioned why the government did not look for more potential victims by contacting doctors around the USA who specialise in allergies to alert them to possible StarLink reactions. The panel suggested that the government data on self-reported allergic reactions might fall far short of actual cases. A spokesman from the FDA agreed: "This passive surveillance system is not complete by any means" said Dr. Karl Klontz. But officials said they lacked the financial resources for carry out wider testing.

Dr. Finger maintains that his reaction was a result of eating a food product contaminated by StarLink. "I know I'm definitely allergic to it. I want accountability – the EPA and FDA should proceed with some very detailed testing of StarLink's health effects. As far as I'm concerned, the FDA did a totally inadequate job of protecting the public" he said.

JAPAN : GM POTATOES IN 'PRINGLES'

Food giant Proctor and Gamble has been forced to pull 800,000 packets of its 'Pringle' chips off the Japanese market after it was discovered that they contain unapproved varieties of GM potatoes. The 'Pringles' were manufactured in the US using Monsanto's NewLeaf Plus and NewLeaf Y potato varieties which have been genetically modified to be resistant to insects and viruses. The potatoes are not approved by the Japanese health authorities.

Following an investigation by Friends of the Earth Europe, Proctor and Gamble said that there is no possibility of the same potato chips being present on the EU. In a written response, a P&G spokesman said that products sold in the European Union are manufactured at the company's European facility from non-GM potato sources. "Specifically, Pringles sold by P&G in the EU are produced with potatoes grown exclusively within the European Union; as you know, no commercial cultivation of GM potatoes is approved in the EU. We work with our suppliers to obtain certification to this effect" the statement said.

Proctor and Gamble do, however, import a US-manufactured potato-based snack into the EU, specifically 'Ridges' which is sold in the UK. In order to comply with EU regulations on GM products, P&G does batch testing on each production run to ensure no GM material is present. "... we source non-GM potatoes for this variety and we carry out analysis on batches to confirm compliance" said the company spokesman.

THE BEE GOES EAST! GMO POLLUTION SYMBOL TRAVELS TO THE BALTICS



After quite a few journeys round a number of EU countries, FoE's 2-metre high Bee, symbol of the European campaign to 'Halt GMO Pollution', is now headed east. From 13-27th August 2001, GMO campaigners and volunteers from Estonia, Latvia, Lithuania and Denmark will join for a 2-week tour through the Baltic countries and Denmark (see schedule below). The aim of the tour is to spread information about the environmental and health effects related to the deliberate release and marketing of GMOs.

Every day, the Bee will be on display in different city. Accompanying the bee will be an exhibition of posters in national languages, an adult competition and a drawing competition for children. Volunteers will distribute leaflets in the national languages and there will be plenty of possibility for interested persons to discuss the issue with one of the GMO campaigners.

Legislation

Although all 3 Baltic countries are in the process of adopting, or have already adopted, legislation on GMOs, public awareness about GMOs is still rather low. Only a handful of NGOs in the Baltic are working on the issue and many citizens do not even know what GMO actually stands for. The legislation in all countries has requirements for public information (applications are made public) and participation (the public/NGOs have the possibility to comment on applications).

In Latvia and Estonia, the law contains provisions for mandatory labelling of GM food, whereas in Lithuania the regulations for labelling GM food are still being drafted. So far, the authorities in

Latvia and Estonia have received no applications for GM food, therefore there are no labelled products in the shops. On the other hand, there are no testing facilities in operation so there hasn't been testing of food products yet. Nevertheless, it's important that before the first GM-labelled food appears in shops, consumers know about the issue to ensure that they have a real choice.

Releases

Although the Lithuanian legislation on GMOs was only adopted a few months ago, there have already been some releases of GMOs in Lithuania. The German company KWS (Kleinwanzlebener Saat-zucht AG), Novartis Seed AB (now Syngenta) and Danish DLF Trifolium have been conducting small scale experimental releases between 1989 and 2000. The releases were herbicide-tolerant sugar beet (Novartis), Roundup Ready fodder beet (DLF Trifolium) and Liberty-tolerant sugar beet (KWS). Although all permits were granted up to 2002, no field trials have been conducted this year according to the authorities.

In Estonia there has been two applications for genetically modified micro-organisms. GM bacteria were used for cleaning water contaminated with phenols due to a fire in an oil shale mine in Ida-Virumaa county, and another GMM was used for cleaning waste water at the Põlva Dairy.

There have already been some releases of GMOs in Lithuania – experimental releases of herbicide-tolerant sugar beet and fodder beet have taken place between 1989 – 2000

After the Bee tour the Baltic GMO Network will focus on seminars and publishing a booklet containing basic information, including a chapter on the legislation and the national situation in each of the three countries.

To learn more about the Baltic GMO Network, contact one of the national campaigners or visit our website (after 13th august 2001) www.baltic-gmo.net

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The Bee's Baltic Tour

Date		City		Country
Sat 11/8	*	Estonian bus to Vilnius	*	
Sun 12/8	*	Meeting in Vilnius to prepare	*	Lithuania
Mon 13/8	*	Vilnius	*	Lithuania
Tue 14/8	*	Kaunas	*	Lithuania
Wend 15/8	*	Klaipeda	*	Lithuania
Thu 16/8	*	Kuldiga	*	Latvia
Fri 17/8	*	Riga	*	Latvia
Sat 18/8	*	Cesis or Valmiera	*	Latvia
Sun 19/8	*	Pärnu – day off	*	Estonia
Mon 20/8	*	Pärnu	*	Estonia
Tue 21/8	*	Tartu	*	Estonia
Wend 22/8	*	Tallinn (ferry from Paldiski in evening)	*	Estonia
Thu 23/8	*	Kappelskär-Copenhagen (travel)	*	Sweden-Denmark
Fri 24/8	*	Roskilde & Party	*	Denmark
Sat 25/8	*	Copenhagen - Departure for Sweden	*	Denmark
Sun 26/8	*	Ferry to Tallinn	*	Denmark-Sweden
Mon 27/8	*	Tallinn – Lithuanian bus to Vilnius	*	Estonia-Lithuania

DENMARK : NEARLY 50% ORGANIC FODDER CONTAMINATED WITH GMOs

NOAH urges feed firms to go GM-free

On 31st July, the Danish food authorities revealed the presence of genetically modified organisms (GMOs) in 20 out of 48 samples of organic animal feed. Twelve samples contained traces of GMO and 8 samples contained more than 1% GMO, of which one sample (a fodder ingredient produced by the company J. B. Møller) contained as much as 100% GMO. These are severe violations of Danish law on organic farming.

The companies were given until 10th August to explain why the contamination happened. If they have no good excuses, Ritt Bjerregaard, Minister of food, agriculture and fisheries (and ex-EU Environment Commissioner), has threatened to notify the violations to the police.

NOAH (Friends of the Earth Denmark) indicated its support for

20 out of 40 samples of organic animals feed contain GMOs – one fodder ingredient contained 100% GMOs

Mrs. Bjerregaard's intention of notifying the police. "Consumers will lose confidence in organic products if rules are violated. Organic farming is the last bastion against genetic engineering. If organic products are contaminated by GMOs, the reliability of organic farming is at risk. Feed companies should not ruin the good reputation of organic farmers" said GMO campaigner Sofie Krogh Andersen of NOAH.

The problem is that Danish feed importers buy animal feed (maize and soya) from countries that produce large amounts of GM crops, in particular the USA and Argentina. For instance, 90% of Argentinian soya is genetically modified

and in the USA more than 50% of the soya and up to 33% of the maize is GM.

NOAH is urging Danish feed companies such as DLG to buy feed from countries that do not grow GM crops. For instance, Brazilian exporters guarantee 100% GMO-free products. Also, Danish and other European fodder crops can be used.

"GMO-free fodder and products from animals fed with GMO-free feed are increasingly in demand, not only by organic farmers but also by consumers in countries such as the UK and Japan which are among the most important purchasers of Danish meat products" said NOAH GMO campaigner Dr. Bo Normander. It would be a great advantage for Danish agriculture if feed companies go completely GMO-free".

FRENCH AGENCY REVEALS WIDESPREAD GMO POLLUTION

According to an article in the French paper *Le Monde* (25.07.2001), presence of GM seed in seeds on conventional variety is growing at an alarming rate. On 23rd July, the Agence Française de Sécurité Sanitaire des Aliments (AFSSA – the French agency for sanitary safety of food) said that "The presence of GMOs in trace amounts in seeds or harvest of conventional varieties seems to have become a reality"; in other words, a 'fait accompli' despite the current EU moratorium.

According to the AFSSA, the likelihood of toxic or allergenic effects of these GMOs is very low. "At this stage, nothing we know of suggests a risk for public health, particularly since the level observed is very low", it said. But, according to *Le Monde*, the "transgenic conquest" is obvious. Nineteen out of 112 twelve samples of oilseed rape, soya and maize seeds, supposedly conventional, which were submitted to AFSSA revealed the presence of the 35S promoter, indicating genetic modification, although levels sometimes did not exceed 0.1%. As far as maize is concerned, 41% of the samples were contaminated. To the AFSSA's surprise, some residues of GM soya were even detected in certain of the maize samples. The AFSSA believes that import of impure seeds is behind the current situation.

The agency tried to counter its rather alarming findings by pointing to other statistics from the *Chambre Syndicale des Entreprises Semencières* (Cooperative Chamber of Seed Companies) which, in the course of testing programme between 2000-2001, found that 7% of conventional maize contained traces of GMOs. Therefore, announced AFSSA, the real

figure for unintended presence of GMOs in maize seed of conventional varieties is somewhere between these two values: 7% - 41%!

Considering that some 3 million hectares in France are used to cultivate maize, *Le Monde* concludes that hundreds of thousands of these hectares probably contain traces of transgenic maize, although only about 34 hectares are actually believed to be used for growing GM maize, solely for experimental trials since farmers have generally shunned the technology. Several things indicate that the spread of GMOs is not under control, the article says, reminding readers that last year the French government had to order the destruction of fields of soya, oilseed rape and maize which were contaminated by illegal GM varieties.

According to François Patriat, French Secretary of State for Small and Medium Enterprises, responsible for GMOs within the government, public controls during the 2000-2001 period indicate "improvements" in controls by producers of GMOs themselves. These controls are intended to ensure that products not authorised in France are not mixed either with approved GMOs or with conventional products. The government is going to ask seed companies to communicate to the authorities what analytical methods they are using. The government also intends to set up a working group of experts, administrative representa-

tives and consumer organisations to develop a charter for transparency on fields trials of GMOs.

Reacting to the news from AFSSA, the French Green Party said in a press statement that it was indicative of an irreversible pollution the long term effects of which on health, agriculture and biodiversity are completely unknown. Calling it 'an accomplice', the Greens said that the European Commission had preferred to listen to a handful of international seed companies, rather than 300 million European citizens. The idea of traceability and transparency have become an illusion since all conventional agriculture will slowly be contaminated by GMOs. Consumer choice also, they said, has become an illusion.

In the same vein, an earlier article in the UK newspaper *The Guardian* (21.06.2001) entitled "When choice becomes just a memory" gave an accurate synthesis of the current situation:

"Europeans would be forgiven for thinking that the war against genetic tampering in the food supply has been all but won..... You'd think that the North American agricultural export industry would have no choice but to bow to the demand: keep GM seeds far away from their unaltered counterparts and, in general move away from the controversial crops.

You'd be wrong. The real strategy is to introduce so much genetic pollution that meeting the consumer demand for GM-free food is seen as not possible. The idea, quite simply, is to pollute faster than countries can legislate – then change the laws to fit the contamination".

41% of the maize samples were contaminated - some residues of GM soya were even detected in certain of the maize samples

UNAUTHORISED AND UNLABELLED GM SOYA IN POLAND

Environmental groups have revealed that a soya product sold in Poland by the Czech company 'Santé' contains 4% GM soya. The product was purchased in Poland in February 2001 and sent to FoE in the US for testing at the Genetic-ID laboratories.

Under Polish legislation, 'Santé' requires authorisation before marketing products containing GMOs in Poland, and they need to be labelled. The Polish Environment Ministry has only granted two permits so far, one to Monsanto for GM soya beans destined for animal feed, and the other to the Polish company, Polgrunt, for soya flour. According to Ela Priwiezincew of the Polish NGO Socio-Ecological Union, the 'Santé' product was neither approved, nor labelled. "The Polish regulation is just a paper tiger since there is no laboratory undertaking routine testing for the presence of GMOs, and no authority has been designated responsibility for enforcing the law" she said.

Iza Kruszewska of ANPED, the Northern Alliance for Sustainability which supports environmental groups in the CEECs, said that worse will come when Poland joins the EU. "After accession, those GM products that are illegal in the EU will have to be taken off the Polish market at high cost. Who will pay the price of recalling thousands of products?" she asked.

DUTCH GOVERNMENT CANCELS FIELD TRIAL PERMITS

Six permits for GMO field trials by the seed company Advanta have been cancelled by the Dutch Ministry of Environment. The six trial permits, involving different kinds of genetically modified sugar beet and oil-seed rape were already suspended last year November by the Council of States.

The court case for the definite ruling had been planned for 19th June 2001 but, with the cancellation of the permits by the Ministry of Environment the court case has also been cancelled. The six permits would have involved a total number of 40-50 field trials. Most likely Advanta will now carry out these trials abroad.

In the meantime, the number of field trials taking place in the Netherlands has dropped sharply this year to only eleven. These involve potato (4x), sugar beet (2x), apple trees (1x), soil bacterium in wheat (1x), and carnations (3x).

(courtesy of Wytze De Lange)

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